



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 7, 2020

Jennifer Reeder
Director, Regulatory Affairs
STERIS Corporation
P.O. Box 147
St. Louis, MO 63166-0647

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Spor-Klenz Ready to Use
EPA Registration Number: 1043-119
Application Date: March 16, 2020
Decision Number: 560833

Dear Ms. Reeder:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

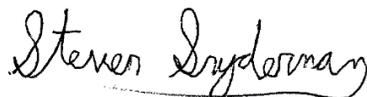
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup are large non-enveloped and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Murine Norovirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

STERIS

**SPOR-KLENZ® Ready To Use
COLD STERILANT**

Reorder Number:	Net Contents:
6525-M2	850 mL (28.7 fl. oz.)
6525-01	3.2 L (3.38 qts.)
6525-P4	189.25L (50 gal.)
6528-73	1 qt. (946 mL)

For Use in Pharmaceutical, Medical Device, Biotech and Cosmetic Manufacturing Facilities

Sterilant/Sporicidal, Bactericidal, Tuberculocidal, Fungicidal, *Virucidal, Non-food Contact Sanitizer

Uses: Primarily intended for sterilization or disinfection of: stainless steel, plastic items and surfaces, hard surfaces e.g. counter tops, floors, walls, bathroom fixtures, glass, formica, vinyl.

Active Ingredients:

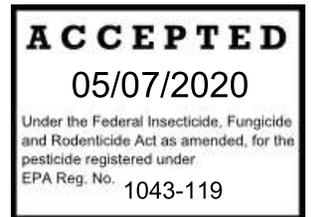
Hydrogen Peroxide	1.00%
Peroxyacetic Acid	0.08%

Inert Ingredients:

98.92%

Total

100.00%



**KEEP OUT OF REACH OF CHILDREN
DANGER PELIGRO**

See side panel for precautionary statements

FIRST AID	
If inhaled	<ul style="list-style-type: none"> •Move person to fresh air. •If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. •Call a poison control center or doctor for further treatment advice.
If on skin or on clothing	<ul style="list-style-type: none"> •Take off contaminated clothing. •Rinse skin immediately with plenty of water for 15-20 minutes. •Call a poison control center or doctor for treatment.
If in eyes	<ul style="list-style-type: none"> •Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. •Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none"> •Call poison control center or doctor immediately for treatment advice. •Have person sip a glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day or night (800) 424-9300, (703) 527-3887.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact Chemtrec at 1-800-424-9300 for emergency medical treatment information.	
Note to Physician:	
Probable mucosal damage may contraindicate the use of gastric lavage.	

EPA Reg. No. 1043-119 EPA Est. No. 52252-MN-01

LOT:
MFD:
EXP:

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals.

DANGER – PELIGRO. Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin. Do not get in eyes, on skin, or on clothing. Avoid contact with skin. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash hands before reuse. Caution should be used when applying indoors because pets may be at risk.

Personal Protective Equipment (PPE): Handlers must wear: Goggles or face shield, and protective rubber gloves.

Environmental Hazards: This pesticide is toxic to birds, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage plant authority. For guidance, contact your State Water Board or Regional Office of the U.S. Environmental Protection Agency.

Physical and Chemical Hazards: This product contains an oxidizing agent.

****KILLS HIV- 1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS**

PREVIOUSLY SOILED WITH BLOOD/BODILY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV-1 (Human Immunodeficiency Virus Type 1 - associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks and eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before the application of the sterilant.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

CONTACT TIME: Leave surfaces completely immersed with undiluted SPOR-KLENZ Ready to Use for a minimum of 10 minutes.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE AFTER EXPIRATION DATE. Do not allow SPOR-KLENZ Ready to Use to mix with alkaline substances such as bleach (Sodium Hypochlorite) or other oxidizing agents. Use purified water (e.g. deionized) for making dilutions, cleaning and rinsing. Some materials may be incompatible with SPOR-KLENZ Ready to Use. Test material prior to use. Spor-Klenz Ready to Use has been shown to be compatible with Polyvinyl chloride, polypropylene, polyurethane, aceto-copolymers, polycarbonate, polysulfone, polystyrene, stainless steel. Reuse of diluted SPOR-KLENZ Ready to Use is not recommended.

DIRECTIONS FOR STERILIZATION: SPOR-KLENZ Ready to Use is not to be used as a terminal sterilant on any critical/semi-critical medical device. Remove any obvious debris or organic material from the surface to be sterilized. This can often be accomplished by rinsing with water or by detergent cleaning followed by a water rinse. Immerse the item to be sterilized in a sufficient volume of undiluted SPOR-KLENZ Ready to Use to cover the item and fill all

passages requiring sterilization. Hold in the sterilizing solution for a minimum of 5½ hours at 20°C temperature (68°F). Remove items after 5½ hours and rinse with sterile water until rinse water shows levels of 10 ppm or less. The solution may be used and reused for up to 14 days in a manual system with 5½ hours immersion.

DIRECTIONS FOR BROAD SPECTRUM DISINFECTION/TUBERCULOCIDE/VIRUCIDE* [HIV-1, Mouse hepatitis virus, Murine parainfluenza virus type 1 (Sendai), Mouse parvovirus and Murine norovirus]/ Mycoplasma gallisepticum/ Aspergillus niger: Use only on hard, non-porous surfaces. This product is not to be used as a terminal high level disinfectant on any critical/semi-critical medical device. Remove any obvious debris or organic material from the surface to be disinfected. This can often be accomplished by rinsing with purified water (e.g. deionized), mechanical action, or by detergent cleaning followed by a water rinse. Apply product to hard, non-porous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge, sprayer, or by immersion. Treated surfaces must remain wet for 10 minutes (For *Aspergillus niger*, contact time is 5 minutes) (For mouse parvovirus, keep surfaces completely immersed for 25 minutes). Wipe dry with a cloth, sponge or mop or allow to air dry. For sprayer applications, use a coarse spray device. Spray 6 – 8 inches from the surface, rub with a brush, sponge or cloth. Do not breathe spray.

FOGGING AS AN ADJUNCT TO REGULAR CLEANING AND DISINFECTING: This product may be used in fogging as an adjunct either preceding or following regular cleaning and disinfecting procedures for hard room surfaces. Prior to fogging, remove or carefully protect all food products and packaging materials. Ensure room is properly ventilated. Vacate all personnel from the room during fogging and for a minimum of 2 hours after fogging or until the hydrogen peroxide air concentration is below 0.5 ppm. Fog areas using one quart (946 ml) per 1,000 cu. Ft. (28.3 m³) of room volume with undiluted SPOR-KLENZ Ready to Use solution. Allow surfaces to dry thoroughly before operations are resumed. Note: In all applications, always prepare a new solution daily to ensure effectiveness. Do not reuse solutions. Dispose of any unused solution.

DIRECTIONS FOR USE AS A GERMICIDAL DISINFECTANT SPRAY: Use only on hard, non-porous surfaces. Spray SPOR-KLENZ Ready to Use undiluted onto cleaned surfaces using a plastic spray bottle. Allow to remain on surface for 30 seconds. Let air dry or rinse with purified water, drain off excess water if possible and allow to dry.

DIRECTIONS FOR USE AS A CLEANER/SANITIZER (Non-food contact surfaces): Using water or mechanical action, remove heavy soil or gross filth from hard surfaces such as formica, stainless steel or vinyl surfaces. Apply by cloth, mop or sponge so as to wet all surfaces thoroughly, a freshly made 50X dilution (1 part product to 49 part water) of SPOR-KLENZ READY TO USE, made using purified water, to the pre-cleaned surface or immerse pre-cleaned items to be sanitized in the solution. Allow 5 minutes of contact time. Let air dry or rinse with purified water, drain excess if possible and allow to dry. May not be reused as a cleaner/sanitizer.

DIRECTIONS FOR USE AS A SPORICIDE: Use only on hard, non-porous surfaces. Remove any obvious debris or organic material from the surface to be sterilized. This can often be accomplished by rinsing with water or by detergent cleaning followed by a water rinse. Immerse hard, non-porous surfaces in a sufficient volume of undiluted Spor-Klenz Ready to Use. Treated surfaces must remain completely immersed for 30 minutes. Wipe dry or allow to air dry.

PRODUCT CLAIMS	
Sterilant/Sporicidal [<i>B. subtilis</i> (ATCC 19659), <i>C. sporogenes</i> (ATCC 3584)] Bactericidal Fungicidal Virucidal	undiluted 5 1/2 hours 20°C
Sporicidal – Non-porous Surfaces [<i>B. subtilis</i> (ATCC 19659), <i>C. sporogenes</i> (ATCC 3584)] and <i>Bacillus cereus</i> (ATCC 14579)	undiluted 30 minutes 20°C
Broad Spectrum Disinfectant [<i>Staphylococcus aureus</i> (ATCC 6538), <i>Salmonella enterica</i> (ATCC 10708), <i>Pseudomonas Aeruginosa</i> (ATCC 15442)] Tuberculocidal (<i>Mycobacterium bovis</i> BCG) (Clinical Isolate) <i>Mycoplasma gallisepticum</i> (ATCC 15302) *HIV-1** (Clinical Isolate) *Minute virus of mice (Clinical Isolate) *Murine parainfluenza virus type 1 (Sendai) (ATCC VR-907) *Mouse hepatitis virus (Clinical Isolate) *Murine norovirus (Clinical Isolate)	undiluted 10 minutes 20°C
Mouse parvovirus (Clinical Isolate)	Undiluted 25 minutes at 20°C
<i>Aspergillus niger</i> (ATCC 16404)	undiluted 5 minutes 20°C
Germicidal Spray Disinfectant [<i>S. aureus</i> (ATCC 6538), <i>S. enterica</i> (ATCC 10708)]	undiluted 30 seconds 20°C
Non-food Contact Surface Sanitizer [<i>S. aureus</i> (ATCC 6538), <i>K. pneumoniae</i> (ATCC 4352)]	diluted 50X (1 part to 49 part water) for 5 minutes 21°C

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage:

Store in shipping carton. Do not expose to direct sunlight. Maintain temperature below 75° F (24° C). Avoid contact with combustible materials. Store in original closed container. For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day or night (800) 424-9300, (703) 527-3887.

Pesticide Disposal:

Wastes resulting from the use of this product may be disposed of on-site in a sanitary sewer or at an approved waste disposal facility. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for Guidance.

Container Disposal:

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

(For ≤ 5 gal.): Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

(For > 5 gal.): Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

(Optional Label Text)

Packaged with Sprayheads

Double Bagged

ETO Exposed Packaging

ETO Processed Packaging

ETO Process Packaged

Ethylene Oxide Exposed Packaging

Ethylene Oxide Processed Packaging

Manufactured for:

STERIS Corporation

7501 Page Avenue

St. Louis, MO 63133 U.S.A.

800-548-4873 www.steris.com

Product Made in U.S.A.

Emerging Viral Pathogens Claims

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- Enveloped Viruses
- Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...follow the directions for use for the following organisms on the label:
Enveloped virus	Murine Norovirus
Large, non-enveloped virus	Murine Norovirus

Acceptable claim language:

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against Murine Norovirus on hard non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Murine Norovirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.